K120302

510K SUMMARY
FOR
NOVAF OCEANIC WHEELCHAIR

JUL 6 2012

SPONSOR:

Novaf Andalucia 2007, S.L.
Camino de Santa Teresa , Nave 1
11520 Rota (Cádiz)
Spain

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DATE PREPARED: July 2nd, 2012

DEVICE NAME:

Propietary Name:	The Oceanic
Generic Name:	Manual Wheelchair
Device Name:	Mechanical Chair
Models:	Oceanic/Oceanic Baby

PREDICATE DEVICES:

DB Perks and Associates Steel Aquatic Chair	K031910
Landeez All-Terrain Sport Chair	K954261
Vipamat Technologie Hippocampe Wheelchair	K051709

FDA PRODUCT CODE:	IQC
FDA CLASSIFICATION:	Class II
PANEL CODE:	Physical Medicine
REGULATION NUMBER:	890.3880

DEVICE PRESCRIPTION:

The Oceanic Wheelchair is a wheelchair suitable for use on different terrains and also in water. It can be used on surfaces like sand, snow, gravel, grass and in water. The user must be accompanied at all times, since it can not be driven by the person sat on it.

This is a very long life product with the following components:

- Wheelchair
- Foldable armrests
- Foldable footrest
- Starring/traction bar

The Oceanic is available in large (Oceanic) and small (Oceanic Baby) configurations which vary in length and also in the width and height of the seat. The Oceanic Baby and Oceanic intended use is the same, but the Oceanic Baby has a maximum weight load of 50kg while the maximum weight load for the Oceanic is 100kg.

All parts on our wheelchair are fabricated from aluminium and selected materials suitable for use in an aquatic environment. The chair can be submersed in water without any harmful effects.

Users manual provides information on warnings, cautions, maintenance and operation instructions.

INTENDED USE

This wheelchair is a manual attendant-operated wheelchair intended to provide mobility to people with reduced-mobility problems.

SUBSTANTIAL EQUIVALENCE

The Oceanic is substantially equivalent to the predicate devices listed above. The all have similar technological characteristics and indications of use. The overall design of the Oceanic and the predicate wheelchairs are similar too. All of them are suitable to be used in various kind of water (pools, oceans, lakes and ponds). All these devices consist of 3 or 4 wheels with a chassis and a push bar. The Hippocampe has three wheels like the Oceanic while the other two have four. This difference does not affect the safety or effectiveness of the Oceanic as safety tests (stability tests) has been carried out successfully using the Oceanic.

A minor difference between the Oceanic and the Hippocampe and BD Perks is that the Oceanic does not have a pushbar, but just because it compromises a steering/traction bar to be propelled. The Landeez is also intentded to be used with the help of an attendant.

PERFORMACE TESTING

Testing has been performed to evaluate the overall stability, dimensions and mechanics of the Oceanic. The testing showed that the Oceanic is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Novaf Andalucia 2007, SL
% Mr. Fernando Saenz De Santamaria
Camino Se Santa Teresa
Nave 1
Rota, Spain PC 11520

JUL 6 2012

Re: K120302
Trade/Device Name: Oceanic
Regulation Number: 21 CFR 890.3880
Regulation Name: Special grade wheelchair
Regulatory Class: II
Product Code: IQC
Dated: June 28, 2012
Received: June 28, 2012

Dear Mr. Saenz De Santamaria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120302

Device Name: Oceanic

Indications For Use: The Oceanic is a manual attendant-operated wheelchair intended to provide mobility to people with reduced-mobility problems.

Prescription Use _____ AND/OR Over-The-Counter Use _____X_
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120302